REMARKS/ARGUMENTS

This document responds to the Office Action mailed on June 5, 2009. In that Office Action, claims 1-9, 10-11, and 13-15 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over DeSatnick et al. (USPN 4,650,462) in view of Wheeldon et al. (USPN 4,670,007). Claims 12, and 16-18 rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over DeSatnick, in view of Wheeldon, and further interview of Maddock et al. (USPN 5,549,672). Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

Claim Rejections of Claims 1-9, 10-11, 13-15 -- Under 35 U.S.C. § 103

Claims 1-9, 10-11, and 13-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over DeSatnick et al. (USPN 4,650,462) hereinafter "DeSatnick" in view of Wheeldon et al. (USPN 4,670,007) hereinafter "Wheeldon." Applicant respectfully traverses this rejection, because DeSatnick and Wheeldon, alone and in combination, fail to teach all of the elements of the claims.

Claims 1-9

Applicant believes that claims 1-9 as currently pending are patentable over the combination of DeSatnick and Wheeldon. Nevertheless, claim 1 has been amended to further distinguish from the cited references in order to expedite allowance of subject matter in the present application.

In rejecting the claims, the office action asserts that DeSatnick teaches "a system for delivering a volume of sterile fluid to a targeted anatomical site." *Office Action 6/5/09*, p. 2. Applicant respectfully disagrees. Nevertheless, claim 1 has been amended to more specifically indicate that the volume delivered is a "desired volume."[1] This further distinguishes from

[1] The present application describes a system and method in which a volume of fluid is delivered to a surgical site, for example in a lipoplasty procedure, to produce a "desired final result." *Specification*, p. 2, ln. 11. The application further states "[s]imilarly, cosmetic surgery frequently involves the insertion of devices, e.g., plastic breast implants or temporary sizers, that are filled with sterile fluid to the desired amount. Again, it is highly desirable that the surgeon be able to insert the fluid rapidly in the precise volume." *Specification*, p. 2, lns. 14-17. The phrase

DeSatnick which does not provide for delivering a "desired volume" of fluid. Rather, DeSatnick is directed to an irrigation system such as used in arthroscopic surgery that "allows independent control of both pressure and ***flow***." *DeSatnick*, col. 2, lns.10-11 (emphasis added). The system of DeSatnick delivers a continuous flow of fluid and not a "desired volume."

DeSatnick is a system for irrigating a surgical site, particularly in arthroscopic surgery. *See DeSatnick*, Title; col. 1, lns. 5-7. "Irrigation" refers to a process in which fluid is injected into the surgical site and simultaneously removed from the site. *Id. at* Abstract; *see also,* Fig 1 showing inflow line 20 into the surgical site and outflow line 24 from the surgical site. DeSatnick describes the purpose and requirements for "irrigation" as follows.

> During the surgery, irrigation of the joint is necessary for the following reasons:
>
> (1) Inflation of the joint is desirable for better visualization and access achieved by an increased joint or tissue separation. This is accomplished by application of pressure through the medium of the irrigation fluid.
>
> (2) Flow of the irrigation fluid through the joint keeps the field of view clear and eliminates any loose debris.
>
> (3) The fluid keeps the joint lubricated and replaces lost body fluids.
>
> ***There are thus two independent factors at work here, the pressure and the flow rate of the irrigation fluid.***

Id. at col. 1, lns. 14-26 (emphasis added). According to DeSatnick:

> The system of the invention does what none of the currently available systems do--it permits independent control of the pressure and flow rate values and it automatically adjusts the outflow and, if necessary, the pump speed to maintain the selected pressure.

Id. at col. 6, lns. 23-26. The desired pressure to be maintained at the surgical site is preselected by the attending physician, the pressure of the fluid leaving the surgical site is measured and

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"desired amount of sterile fluid" was used in claim 10 of the application as it was originally filed and published.

monitored, and the flow rate of fluid delivered to the site is adjusted to maintain the desired pressure.

As illustrated in FIGS. 1 and 2, the system of DeSatnick includes an inflow line 20 and outflow line 24 through which the fluid is delivered to and drained from a body site. As noted by DeSatnick, "[t]he pump 12 will preferably be a peristaltic pump with three manual RPM settings 14 for selectively providing ***constant*** low, medium or high flow." *Id* at col. 3, lns. 52-55 (emphasis added). As this statement indicates, DeSatnick teaches delivery of fluid at variable flow rates to maintain a desired pressure and not delivery of a "desired volume" of fluid, as recited in claim 1. Simply stated the volume of fluid delivered to or retained at the surgical site is not one of the factors involved in proper irrigation by the DeSatnick method. Volume is not measured, and the delivered volume or retained volume is not displayed by the DeSatnick controller.[2]

DeSatnick further teaches against the delivery of a "desired volume" of fluid. The system of DeSatnick is intended to be used in Arthroscopic surgery procedures which as noted by DeSatnick requires "[f]low of the irrigation fluid through the joint [to keep] the field of view clear and [eliminate] any loose debris." *Id* at col. 1, lns. 20-22. Additionally, DeSatnick states:

> The proposed irrigation system is unique in that it allows independent control of both pressure and flow. The system can be set to operate at any preselected values of pressure and flow rate. Once these are selected, the system automatically operates to maintain these values. If, however, there is a conflict between achieving these two values (due to leakage, etc.), it is the pressure value that will be maintained at the expense of the flow rate. ***This is because, of the two, pressure is the more critical factor. An increased pressure can cause damage to the body.*** It can lead to fluid extravasation (seepage) into the surrounding soft tissues and if high enough, can rupture the capsule. High pressures can be caused by increased fluid inflow and very high pressures can also

[2] "Volume" is misused by DeSatnick interchangeably with "flow rate." *See, e.g.*, col. 3, lns. 9-20. That "volume" is misused by DeSatnick is demonstrated by the fact that DeSatnick does not disclose any means to measure or alter a desired volume. Pressure and flow rate are the only two factors identified, measured and controlled. No means are described in the specification to measure or control a volume of fluid. As depicted in Figure 1, the controller 10 only has adjustments for pressure ("press") and flow rate ("flow").

> occur when a joint is flexed. Thus, continuous monitoring and control of pressure in the cavity are necessary and important.

Id. at col. 2, lns.15-27 (emphasis added). Thus, the system of DeSatnick would be unsuitable for its intended purpose if used to deliver a "desired volume" because once the desired volume is delivered, no additional fluid would be delivered for example to clear debris. Also, in situations were the pressure becomes too high, delivering the "desired volume" may cause damage to tissues. For at these reasons, a person of ordinary skill in the art would be guided away from modifying the system of DeSatnick to deliver a "desired volume" of fluid.

Further, neither DeSatnick nor Wheeldon teach "wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," as recited in claim 1. With respect to the combination of DeSatnick and Wheeldon, the office action states that "[t]he examiner does not believe that making this combination requires the addition of the control feature of Wheeldon to the device of DeSatnick because Wheeldon is only being relied upon to teach that using the strain gauge and the processor is a more accurate and desired way of monitoring the flow rate and volume than just relying on a calibration of the RPM reading." *Office Action 6/5/09*, p. 5. Applicant respectfully disagrees.

The ability to control flow rate, and not just monitor it, is one of the objectives of DeSatnick. *See DeSatnick*, col. 2., lns. 10-11 ("[t]he proposed irrigation system is unique in that it allows ***independent control of both*** pressure and flow."). Incorporating the strain gauge and the processor from Wheeldon, to simply monitor the flow rate, without providing for control of the flow rate would defeat the purpose of having the additional accuracy and precision. DeSatnick's teachings would guide a person of ordinary skill in the art to use the strain gauge and processor from Wheeldon to control the flow rate, which would require output from the processor to be electronically connected to the pump. Accordingly, not only do DeSatnick and Wheeldon fail to teach "wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," as recited in claim 1, DeSatnick would guide a person of ordinary skill in the art away from such a feature.

The combination of DeSatnick and Wheeldon thus fails to teach all of the elements of claim 1 and teach away from the combination of features of claim 1. Claims 2-9 depend upon claim 1 and are allowable for at least the same reasons.

Claims 10, 11, & 13-15

Independent claim 10 is directed to "a method for rapidly delivering and accurately monitoring the delivery of a desired volume of sterile fluid to a targeted anatomical site or implantable device." Claim 10 includes features similar to claim 1. Specifically, claim 10 provides for delivering "a desired volume" of sterile fluid. Also, claim 10 recites "wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," which is not taught or suggested by the combination of DeSatnick and Wheeldon. The combination of DeSatnick and Wheeldon thus fails to teach all of the elements of claim 10 and indeed teach away from the combination of features recited in claim 10. Claims 11 and 13-15 depend upon claim 1 and are allowable for at least the same reasons.

Claim Rejections of Claims 12 and 16-18 -- Under 35 U.S.C. § 103

Claims 12 and 16-18 where rejected based on DeSatnick in view of Wheeldon and further in view of Maddock. Claims 12 and 16-18 depend upon independent claim 10 and are allowable over DeSatnick and Wheeldon for the same reasons as noted above with respect to claim 10. Furthermore, Maddock does not compensate for the deficiencies in DeSatnick and Wheeldon. Claims 12 and 16-18 are therefore allowable over the combination of DeSatnick, Wheeldon, and Maddock.

Conclusion

This document responds to the Office Action mailed on June 5, 2009. Still, the Office Action may contain arguments and rejections that are not directly addressed by this document because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this document to directly address an argument raised in the Office Action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the Office Action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this document, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability.

No fees are believed due. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

In light of the above remarks, it is believed that the application is now in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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